

## **REMARKS**

### **A. Status of the Claims**

Claims 9-10 and 14-22 are pending in the application.

### **B. The Claims Are Patentable Over Fuchs in View of SU 1740002 or Buhlbacker**

The Action continues to reject claims 9-10 and 14-22 under 35 U.S.C. § 103(a) as obvious over Fuchs *et al.* (WO 01/97634 A1) in view of SU 1740002 (as explained in the Russian Search Report) or Buhlbacker. Applicant traverses this rejection.

The currently claimed method provides surprisingly successful results in treating neurodermatitis and psoriasis that would not have been expected from the disclosures of Fuchs *et al.* (WO 01/97634 A1), SU 1740002, and Buhlbacker. The evidence in the specification and the Fuchs Declaration, which was discussed at length in Applicant's previous response and incorporated here by reference, demonstrate that the claimed method is not only therapeutically effective, but that it is therapeutically effective in a short period of time (*i.e.*, in less than three months, and in many cases in one month).

The current Office Action states that the obviousness rejection relies upon the teaching of Buhlbacker and SU 1740002 to add additional motivation to the teaching of Fuchs that applying the composition of Fuchs to the treatment of neurodermatitis and psoriasis would be obviously beneficial (Action, p. 3). The teachings of the references do not, however, support the Action's theory. While Fuchs discloses that milk may be added to a matrix and fatty acid mixture before drying (Fuchs translation, p. 15), there is no specific disclosure or suggestion that a milk concentrate dried on a biologically inert, disperse matrix can be used in a method treating neurodermatitis or psoriasis. Buhlbacker studied dietetic treatment with *native* mare's milk and found that a minimum treatment time of **10 months** was required. In addition, Buhlbacker reported that mare's milk was *ineffective* in treating neurodermatitis if given alone. There is no

teaching in any of the cited references that drying a mare's milk concentrate on a biologically inert, disperse matrix would improve the efficacy a method treating neurodermatitis or psoriasis.

Nevertheless, the Action alleges that the improved efficacy in treating neurodermatitis or psoriasis would have been obvious because Fuchs characterized his composition as being an improvement over the prior art. Such a generalization does not, however, support a conclusion of obviousness. Applicant's review of the translation of the Fuchs' reference indicates that the word "improve," "improvement," or "improved" was used only once, and this was in regard to improved shelf life of the product (Translation, p. 10, ln. 3). Moreover, much of the Examiner's arguments are based on presumed intentions, not facts. Fuchs discloses that highly unsaturated fatty acids are important for skin metabolism, and that highly unsaturated fatty acids occur mainly in plant oils and fish oil (Fuchs translation, p. 3). Fuchs also discloses that milk *may* be added to the matrix and fatty acid mixture before drying (Fuchs translation, p. 15). From this, the Examiner makes the conclusory assertion that Fuchs "clearly intended" to include mare's milk in the formulation and use that formulation in the treatment of neurodermatitis and psoriasis. Factual findings made by the Examiner are the necessary underpinnings to establish obviousness. MPEP § 2141. The Examiner's presumed intentions of the Fuchs' reference have not been supported by factual findings. In particular, there are simply no identified facts that support the Examiner's conclusion that a person of ordinary skill in the art would have expected that the a mare's milk concentrate dried on a biologically inert, disperse matrix would be more effective at treating neurodermatitis or psoriasis than the native mare's milk disclosed in Buhlbacker.

Moreover, the teachings of Buhlbacker and SU 1740002 would actually have led a person of ordinary skill in the art in a direction completely different from that recited in the currently claimed method. SU 1740002 describes the use of koumiss as a dietary supplement in the treatment of neurodermatitis and eczema. The fermentation process used to make koumiss

results in a number of changes to the milk. As noted in SU 1740002, the sedative effect of koumiss, which is likely due to the alcohol content, results in more sound sleep, reduction in skin itching, and relief of high nerve excitability (SU 1740002 at page 4). In addition, SU 1740002 discloses that koumiss has antibacterial properties (SU 1740002 at page 4), which are likely attributable to the active cultures involved in the fermentation process.

Thus, to improve efficacy of mare's milk in treating neurodermatitis and psoriasis, the teachings of Buhlbacker and SU 1740002 would suggest to a person of ordinary skill in the art that one would need to ferment the mare's milk. There is no teaching or suggestion that drying the mare's milk would have a beneficial effect. Moreover, the drying process would be incompatible with the teachings of SU 1740002 regarding the sedative effect of the alcohol in the koumiss, which results in more sound sleep, reduction in skin itching, and relief of high nerve excitability (SU 1740002 at page 4). Drying would result in the loss of the alcohol through evaporation. Thus, drying koumiss would deprive it of the benefits of more sound sleep, reduction in skin itching, and relief of high nerve excitability attributed to the alcohol by SU 1740002. If a proposed modification would render the prior art being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. MPEP § 2143.01(V). If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP § 2143.01(VI).

For at least the reasons discussed above, the current claims are non-obvious over Buhlbacker, Fuchs, and SU 1740002. Applicant, therefore, requests the withdrawal of this rejection.

**C. Conclusion**

Applicant believes this to be a complete reply to the Office Action dated December 22, 2008. The Examiner is invited to contact the undersigned attorney with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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